

## **Electronic Cigarettes**



Electronic cigarettes (e-cigarettes or electronic nicotine delivery systems (ENDS)) are devices that claim to contain no tobacco or stem material, but are designed to look like conventional cigarettes. They produce a mist or vapor upon each inhalation by the user that resembles and tastes like the smoke produced by conventional tobacco products. E-cigarettes are intended to be manipulated and used (inhaled) in ways similar to how a smoker manipulates and uses conventional cigarettes and other tobacco products.

They come in a variety of flavors, many that may be appealing to children and young adults. Most e-cigarettes claim to deliver nicotine; however some do not. The amount of nicotine varies widely based on cartridge brand and strength, but is generally 6-18mg nicotine per cartridge. Zero nicotine cartridges are also offered. Cartridges are equivalent to about ½ of a pack to 1½ packs of cigarettes.

These products are designed with a rechargeable battery-operated heating element that volatilizes the chemical constituents contained within replaceable cartridges. These cartridges may or may not include nicotine. Thus, these "electronic" cigarettes and their components are intended to affect the body's structures and functions and/or to treat or prevent withdrawal symptoms of nicotine addiction.

Manufacturers include Ruyan and Sailebao (under brand names NJOY and Smoking Everywhere). Retail outlets selling ecigarettes include mall kiosks, Pilot Travel Centers, Kangaroo Convenience Stores, Travel Centers of America, Petro Shopping Center, Smoker Friendly, and various websites.

## The concern over these products

While e-cigarettes/ENDS are viewed by some as a potentially less dangerous alternative to cigarettes or a potential smoking cessation aid, at this time there is no publicly available independent research on the critically important question of safety or efficacy. Electronic cigarettes have not been approved as safe by the U.S. Food and Drug Administration (FDA) and are currently under investigation.

Another concern is that some smokers are buying empty liquid cartridges and filling them themselves with solutions purchased online. Various companies sell flavored nicotine solutions for this purpose. A wide array of flavors is available, many of which are candy/fruit flavors, including vanilla, chocolate, apple, banana, blueberry, strawberry, grape, menthol, coffee, cola, bubble gum, almond, vanilla ice cream, cherry, mint, peach cobbler, and mint chocolate.



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Refill bottles are offered in different strengths, some as high as 36mg/ml. of nicotine. Different solution makers use different concentration methods. When a bottle is labeled 18mg, it may mean that it's 18mg nicotine per milliliter or 18mg per 1.4ml, depending on the manufacturer.

The solutions are very concentrated. Therefore a 30ml (about 1 oz) bottle of e-cigarette solution can easily contain 500+ mg of nicotine. Some may even be over 1,000 mg per bottle. This creates a risk of overdosing or poisoning, because the lethal dose of nicotine for adults is 30-60mg if swallowed, and for children is just 10mg. Solutions come in a small bottle, often fruit-flavored and without a child safety cap.

## What to do?

There is no data establishing that these products are safe and effective for treating nicotine dependence according to scientific experts. Furthermore, the electronic nicotine delivery systems (ENDS) and their components are not subject to the Federal Cigarette Labeling and Advertising Act (FCLAA), nor are they subject to the Comprehensive Smokeless Health Education Act (CSTHEA). Thus, they do not fit within the regulatory scheme that Congress has established for tobacco products. Therefore, the marketing of these ENDS in the United States as a cessation aid is a violation and is subject to enforcement action.

There are numerous methods for treating tobacco use addiction that have been thoroughly researched and are endorsed by health care professionals. Specifically, the US Public Health Service issued the 2008 Guideline on Treating Tobacco Use Addiction. There are seven first line medications that FDA has approved for treating tobacco use addiction, and e-cigarettes are not one of these first line medications. Consumers need to know that e-cigarettes are not an approved quit smoking device. Promotion of these products as a cessation aid without approval from the FDA is prohibited.

On September 10, 2010, the FDA issued warning letters to five electronic cigarette distributors for various violations of the Federal Food, Drug and Cosmetic Act (FDCA), including unsubstantiated health claims and poor manufacturing practices. The FDA also stated that electronic cigarette products are now subject to the same FDA regulation as other drugs, which means they would have to comply with the FDA's drug approval process and meet the same safety, efficacy and manufacturing standards as other drugs, including nicotine replacement therapy.

For more information on the FDA's enforcement action, visit: <a href="http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm">http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm</a>

Electronic cigarettes are not an evidence-based, safe or effective method for treating nicotine addiction. Smokers wanting to quit should contact a health care provider for assistance and call 1-800-QUIT-NOW for evidence-based advice.